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### **REMARKS**

Claims 1, 2, 6 and 10 through 12 are pending in the application.

Claim 1 has been amended to reflect the 35 U.S.C. §112 rejection.

Applicants respectfully submit that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

#### **Rejection under 35 U.S.C. §112**

The Office Action rejected claims 1, 6 and 10 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. It is the Examiner's position that the phrase "and the salt is water soluble and further exhibits improved water solubility in comparison to the amino acid alone" constitutes subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have deleted the phrase "and the salt is water soluble and further exhibits improved water solubility in comparison to the amino acid alone" from claim 1. Therefore, the rejection under 35 U.S.C. §112, first paragraph should have been overcome.

#### **Rejection under 35 U.S.C. §103(a)**

Claims 1, 2, 6, and 10-12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Nakajima (EP 0122400), Ebisawa et al, and Ninomiya et al (GB 1297741) in view of Ledniczky et al (WO 99/04822) and Rayburn (WO 00/12067). It is the Examiner's position that Nakajima discloses a sweetener composition comprising acesulfame K and an amino acid. Ebisawa et al. disclose the crystallization of aspartame with amino acids. Ninomiya et al. disclose the combination of saccharin and tryptophan. It is

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acknowledged that the claims differ as to the specific recitation of a salt. However, Ledniczky et al. disclose a salt of a sweetener where the salt provides beneficial organoleptic properties. Rayburn discloses a salt of saccharin for improved organoleptic properties. The Office Action then contends that it would have been obvious to a person of ordinary skill in the art to produce a salt of any of the components of Nakajima, Ebisawa et al, and Ninomiya et al as taught by Ledniczky et al and Rayburn because the preparation of a salt of an intense sweetener improves the organoleptic properties of the sweetener. It is not seen where Applicant has established anything other than expected results. It is held that in the absence of unexpected results, it is not seen how the claimed invention differs from the teachings of the prior art. The Examiner concludes that Applicant's claims are drawn to a combination of known components which produces expected results (reference is made to In re Kerkhoven 205 USPQ 1069 and In re Gershon 152 USPQ 602).

The declaration under 37 CFR1.132 filed August 12,2005 is regarded as being insufficient to overcome the rejection of claims 1,2, 6, and 10-12 based upon 35 U.S.C. 103(a) as set forth in the last Office action for the following reasons:

- No data analysis is provided to support the conclusions.
- The showing does not specifically compare to the prior art relied upon.
- Graph 1 is not legible.
- Page 3, section 12 (b) appears to be incomplete.

Applicant respectfully disagrees.

The references cited in the Office Action have been dealt with at length in Applicants' last Amendment. Applicants refrain from reiterating the arguments presented in the last Amendment, however, would like to emphasize that all of these arguments are still valid and rely upon these arguments in this response.

Upon review of the history of this case it seems that there is a basic misunderstanding of the subject matter of the present invention: the claimed compounds are treated as 'combination of matter' (c.f. e.g. Office Action at page 4, last sentence in first paragraph) which is fundamentally wrong.

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The compounds according to the present invention are organic molecules of a homogeneous, uniform composition and no mixtures of two or more individually freely selectable components. The compounds according to the invention can be compared with any new pharmaceutical or newly synthesized organic molecule. Of course – as with any other pharmaceutical or organic molecule, no matter how complex – its individual atomic components such as hydrogen, carbon, nitrogen or sodium, potassium etc. are known. But this does not mean that the complex organic molecule as such is obvious over its known atomic, ionic or even sub-molecular group components. In order for one skilled in the art to make a certain desired organic molecule it takes a plan on how to synthesize the desired molecule from available precursors sometimes over two and more individual process steps. But even with such a plan it is not guaranteed that the synthesis leads to the desired product it may also totally fail. This is why the art of synthesizing organic molecules is inherently unpredictable.

This situation is transferable to the present object of the invention. Before the invention was made it was desirable to have the properties of high intensity sweeteners and amino acids combined in one homogeneous, uniform chemical compound. Of course one could have administered the two compounds separately, but this has the disadvantage of possible separation of the mixture over time which, in turn, leads to over- or under-dosage of one of the components. The inventors of the present invention, therefore, designed a plan of how to make a uniform organic molecule which – as chemically ‘fused’ sub-molecular groups – contained the high intensity sweetener and the amino acid. However, when designing this plan it still remained totally uncertain whether the synthesized new molecule – if it could be synthesized at all - would indeed exhibit the combined properties of the high intensity sweetener and the amino acid. It is known from biologically active compounds such as amino acids and sweeteners that even minimal variations in their chemical structure may lead to a complete loss of the biological activity. Thus, even if the inventors would succeed with their synthesis plan it could not be foreseen whether the new compound would exhibit the property of the amino acid part or the sweetener part or both or none.

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Accordingly, the discovery itself that the newly synthesized compounds exhibited both the amino acid activity as well as the sweetener activity was overall surprising, let alone the fact that the synthesis plan of the inventors indeed worked and yielded in the desired compounds. The additional effect that the new compounds showed improved water solubility over the amino acids came as an additional surprising effect that was unpredicted and unpredictable.

In view of the above, the question that needs to be answered is: can the newly synthesized compounds be rendered obvious by the combination of references as applied by the Examiner? In summary the rationale applied by the Examiner is:

- The cited references show combinations (mixtures) of amino acids and high intensity sweeteners;
- The references further show certain salts of amino acids that exhibit improved organoleptic properties;
- Motivated by the improvement of organoleptic properties it would, thus, be obvious to make salts of amino acids and high intensity sweeteners; even more so because Applicant's claims are drawn to a combination of known compounds which produces expected results (i.e. the art recognized function of the components).

This rejection must fall because a) the motivation to form salts of amino acids is just a motivation to form the specific salts, mentioned in these references. As explained above, the formation of different salts of amino acids does not mean that those would have the same properties as the ones mentioned in the reference. Different chemical composition most likely goes along with different physiological activity. Thus, the skilled artisan would have to face that the organoleptic properties could not be improved by forming other salts than the ones covered by the teaching of these references. Moreover, other salts of those amino acids could most likely not be prepared according to the method described in these references as they would require a different but unknown synthesis plan.

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The rejection must also fail because b) Applicant's compounds are not a combination of compounds. As pointed out in Dr. Burgard's declaration, simply combining a high intensity sweetener with an amino acid does not yield in the claimed compounds; they remain mixtures. Thus, in re Kerkhoven 205 USPQ 1069 and in re Gershorn 152 USPQ 602 do not apply as the subject matter claimed is no combination.

It is Applicant's belief that the Burgard declaration does provide data analysis to support the conclusions. E.g. table 2 clearly shows by way of numerical data that the compounds according to the invention have a better water solubility than the mixtures of the prior art. Table 2 also clearly compares mixtures, i.e. the prior art e.g. according to Nakajima, to compounds according to the present invention. Graph 1, which supports the results of Dr. Burgard's testing will be provided herewith in a scaled up form for better readability. It clearly shows the different taste profiles of a) a mixture according to the prior art and b) the homogeneous compounds according to the present invention. Specifically the sweetness intensity, perception of sweetness and duration of sweetness are clearly distinct. Finally page 3, section 12(b) is provided herewith with completed information about the source of sodium saccharin.

Applicants, thus, respectfully submit that the claimed invention is patentable in light of the art of record, considered either alone or in combination.

### **CONCLUSION**

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1, 2, 6 and 10 through 12 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional

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extensions or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at facsimile number (571) 273-8300 on January 2, 2006.

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